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APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/018,242	10/01/2002	Goran Aslin	P4811US00/EB/MR	8790	
466	7590 01/22/2004		EXAMINER		
YOUNG & THOMPSON			KOKABI, AZADEH		
	23RD STREET 2ND FL N,  VA   22202	OOR	ART UNIT	PAPER NUMBER	
			3743	10	
			DATE MAILED: 01/22/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

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		A	pplication No.	Арр	licant(s)				
		1	10/018,242	ASL	IN ET AL.				
Offic	ce Action Summary	E	xaminer	Art	Jnit				
		_	zy Kokabi	3743					
The MA Period for Reply	ILING DATE of this commu	nication appea	rs on the cov r shee	t with the corres	oond nce add	Iress			
THE MAILING  - Extensions of time after SIX (6) MON  - If the period for re  - If NO period for re  - Failure to reply wit  - Any reply received	D STATUTORY PERIOD F DATE OF THIS COMMUN e may be available under the provisions: ITHS from the mailing date of this com- ply specified above is less than thirty (i ply is specified above, the maximum s thin the set or extended period for reply by the Office later than three months in adjustment. See 37 CFR 1.704(b).	IICATION. s of 37 CFR 1.136(a munication. 30) days, a reply witt tatutory period will a y will, by statute, cau	). In no event, however, ma hin the statutory minimum c pply and will expire SIX (6) ise the application to becom	ay a reply be timely filed of thirty (30) days will be MONTHS from the mains ABANDONED (35 L	f considered timely. ling date of this coi	mmunication.			
1) Respons	sive to communication(s) file	ed on <u>24 Nove</u>	ember 2003.						
2a)⊠ This acti	on is <b>FINAL</b> .	2b)⊡ This act	ion is non-final.						
3)☐ Since thi closed in	is application is in condition n accordance with the pract	i for allowance ice under <i>Ex p</i>	except for formal n	natters, prosecut C.D. 11, 453 O.0	ion as to the 3. 213.	merits is			
Disposition of Cla	aims								
4) Claim(s)	1-33 and 35-45 is/are pend	ding in the app	olication.						
	4a) Of the above claim(s) is/are withdrawn from consideration.								
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6) Claim(s)	1-6,9,32,38,39 and 41-45 i	is/are rejected							
	are subject to restri								
Application Paper									
9)☐ The spec	ification is objected to by th	ne Examiner.							
	ring(s) filed on is/are		ed or b) objected	to by the Exami	ner.				
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	ent drawing sheet(s) including				• •	R 1.121(d).			
	or declaration is objected t					• •			
Priority under 35	U.S.C. §§ 119 and 120								
a)⊠ All b)[ 1.□ Ce 2.□ Ce 3.⊠ Co ap * See the at	edgment is made of a claim  Some * c)  None of:  entified copies of the priority entified copies of the priority opies of the certified copies plication from the Internation tached detailed Office action	documents had documents had of the priority onal Bureau (Pon for a list of the	ave been received. ave been received i documents have be CT Rule 17.2(a)). he certified copies	n Application No een received in t not received.	o his National S				
13) Acknowled since a spe 37 CFR 1.7 a) The 1 14) Acknowled	dgment is made of a claim t ecific reference was include	for domestic production for the first some section of the first some section of the first sec	riority under 35 U.S entence of the spec ional application ha riority under 35 U.S	.C. § 119(e) (to a cification or in an s been received .C. §§ 120 and/o	Application E  . or 121 since a	Data Sheet.			
Attachment(s)									
1) Notice of Referer 2) Notice of Draftspo	nces Cited (PTO-892) erson's Patent Drawing Review (F osure Statement(s) (PTO-1449) P		5) Notice	ew Summary (PTO-4 of Informal Patent A					

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### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1-6, 9, 32, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodson et al (U.S. Patent No. 5,347,998).

Hodson et al disclose a metered-dose breath-actuated inhaler including all the features recited in the claims. The embodiment described with reference to FIGS 6-9 includes an activator for activating a canister to dispense medication in the form of cocking spring or pressure spring means (#86) and vane (#88). Hodson further discloses a return controller or which comprises a spring or return spring means (#99) that controls or biases the rocker element (#90) to a position that prevents activation of the canister when inhalation terminates. Hodson teaches that when a patient inhales through a mouthpiece (#76), the airflow causes pivotal movement of the vane (#88), which causes a curved surface (#96) to rotate and rotate a catch (#92) in an opposite direction. The catch moves from a blocking position to a non-blocking position and permits movement of the rocker element (#90), which in turn moves a canister (#74) relative to a valve stem (#78), thereby firing the valve and releasing a dose of medication. Further, Hodson discloses that the rocker element (#90) is biased by a spring (#99) to its blocking position when patient inspiration is halted" (see at least column 6, lines 25-28).

In reference to claim 9, Hodson discloses monitoring means capable of detecting the time between activation and deactivation of the canister (see at least column 3, lines 60-68). In reference to claim 32, Hodson et al discloses a safety means that prevents activation of the inhaler when the safety means is in a non-operative state. The safety means takes the form of a timing mechanism associated with the priming mechanism for the inhaler (see at least column 7, lines 34-48). Figure 7 shows a housing holding the inhaler (#102).

## Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 5. Claims 38, 39, 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodson et al in view of Wakeman (U.S. Patent No. 3,151,618).

As previously set forth in paragraph 2 above, Hodson et al disclose all the limitations as set forth, however Hodson fails to disclose means for moving the mouthpiece from a rest

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position where the mouthpiece is arranged substantially within a body to an activated position where at least the front end of the mouthpiece protrudes from the body of the inhaler.

Wakeman discloses a canister-type inhaler that includes a mouthpiece (#30) that pivots from a position within the body of the inhaler (figure 1) to a position where the mouthpiece protrudes from the inhaler (see figures 1-4). The mouthpiece is held in the two positions by fixating means comprising a cap (#12) and a surface (#52) of the actuator against which the nozzle rests in the protruding position.

As seen in figures 1-4, the mouthpiece pivots about a pivot axis along a pin (#34) that is journaled in opening (#36). The actuator (#18) acts as a guide means limiting sliding movement of the mouthpiece along a longitudinal direction. The cap (#12) handles/covers the actuator that set the inhaler ready for delivery of a dose of medication.

At the time of invention, it would have been obvious to one with ordinary skill in the art to modify the inhaler taught by Hodson et al to include a pivoting mouthpiece and cap arrangement as taught by Wakeman in order to make the inhaler more compact and less conspicuous when not in use (see Wakeman, at least column 1, lines 35-39).

## Allowable Subject Matter

6. Claims 7-8, 10-31, 33, 35-37, 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Response to Arguments

7. Applicant's arguments filed 11/24/03 have been fully considered but they are not persuasive. Applicant argues that Hodson fails to disclose a return controller that deactivates the

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canister to close the opening when the airflow drops below a certain threshold value (see Applicant' remarks, pg. 22). Applicant argues that the return means of Hodson are all activated by an electrical response from either a time circuit or switches.

However, Hodson specifically teaches that a return controller (#99) controls the rocker element and it biases it back to a blocking position when patient inspiration is halted (see column 6, lines 25-28). Therefore, as patient inspiration is halted, the airflow in the canister drops below a certain value and the rocker element blocks the canister opening. This deactivates the canister. Electrical signs are used to reset the valve for reenergizing after firing of the medication. Furthermore, electromechanical means such as a motor and battery are used in Hodson reference is used to prime the canister for firing.

#### Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Azy Kokabi whose telephone number is (703) 306-4154. The examiner can normally be reached on Monday- Friday, 6:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

1120/04

Supervisory Patent Examinat